

REVIEW OF THE FY2004 SCIENCE AND TECHNOLOGY BUDGET REQUEST FOR THE U.S. ENVIRONMENTAL PROTECTION AGENCY: AN EPA SCIENCE ADVISORY BOARD REVIEW

A REVIEW BY THE U.S. EPA SCIENCE ADVISORY BOARD (SAB) SCIENCE AND TECHNOLOGY REVIEW PANEL

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C. 20460

April 30, 2003

OFFICE OF THE ADMINISTRATOR SCIENCE ADVISORY BOARD

EPA-SAB-EC-03-006

Honorable Christine Todd Whitman Administrator U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, DC 20460

Subject: Review of the FY2004 Science and Technology Budget Request for the

U.S. Environmental Protection Agency: An EPA Science Advisory Board

Review

Dear Governor Whitman:

This letter transmits the advice of the US EPA Science Advisory Board (SAB) on the FY 2004 EPA Science and Technology budget request. This report was developed by the SAB Executive Committee's (EC) Science and Technology Review Panel (STRP), a panel established largely from the SAB's Research Strategies Advisory Committee (RSAC), plus additional SAB members who were added to provide additional expertise and to balance the panel. As in past years, this review was conducted in a rapid response fashion so the report would be available for the House Science Committee's Congressional hearing on EPA's Science and Technology budget. The STRP met, by public telephone conference and in face-to-face meetings, to review the Science and Technology component of the Agency's FY2004 Presidential Budget Request on three occasions during January, February, and March, 2003. The Panel's report was approved by SAB's Executive Committee during a public meeting on April 10, 2003.

As part of the review process, the SAB responded to five charge questions:

- a) Does the budget request reflect priorities identified in the EPA and ORD Strategic Plans?
- b) Does the budget request reflect coordination between ORD and the Program Offices, including identification of the science needed to support major upcoming rules and decisions?

- c) Does the President's Budget request provide adequate balance and attention to the core and problem driven research needed to provide satisfactory knowledge for current and future decisions EPA will be required to make?
- d) Is the EPA research and development program addressing the important issues needed to meet EPA's strategic objectives and protect human health and the environment in the US and globally? What important issues are not receiving adequate attention at the requested level of resources provided for the R&D program and the S&T budget?
- e) How can EPA better use measures of performance that focus on environmental outcomes to identify the impact of its research and development program and the funds that Congress provides for that Program?

Overall, on the basis of its review, the SAB notes that:

- a) The continuing downward trend in science and technology funding for EPA, in real dollar terms, continues to cause the SAB to have concerns about the ability of EPA to meet its strategic goals and objectives for science. Such flat to declining budgets erode the ability of EPA to conduct important research across its programs. The development of high quality science-based regulations is not possible without an adequate research base.
- b) The overall distribution of the Agency's limited science and technology resources by Agency Goal appears to be appropriate.
- c) Given the history of Congressionally added projects in the EPA science and technology budget, the SAB strongly recommends that the Congress add funding to the Agency appropriation to support such projects when they are added to the Agency's budget.
- d) The SAB is pleased that the STAR Fellowships program is restored in the FY 2003 Enacted Budget and recommends that the FY 2004 Fellowships be restored to the fully funded level of the 2003 Enacted budget; further, the SAB suggests that the Agency consider further increasing all the STAR program components in the future.
- e) The Board congratulates the Agency on the significant effort that it has demonstrated in collaboration among the EPA Research and Program Offices during the development of its science and technology program budget. Further, the Agency also demonstrated that its efforts, to collaborate in the planning and conduct of research, extend to other Agencies and institutions that conduct research of importance to human health and environmental protection. The Multi-Year Planning Process (MYP) implemented by EPA is a significant and important part of its approach to ensuring intra- and inter-agency planning of science. These MYPs will be important items for the SAB to consider as it prepares for future evaluations of the Agency's science and technology budgets.

- f) The Science Inventory can be a significantly important tool for EPA to track the science necessary for achieving its mission. If the Inventory is made publicly available, it will significantly contribute to the transparency and accountability of the peer review process.
- g) The review panel observed that the Office of Research and Development (ORD) and the Program Offices do not identify how their science and technology programs are distributed into "core" and "problem-driven" categories to the same degree. Agency Multi-Year Plans demonstrate that ORD clearly recognizes and considers this factor in the development of EPA research programs. Further, ORD refers to this distribution in materials that explain its program. Because EPA ORD's core research often moves rapidly into the applied arena (where it can be used in supporting Agency decision-making), dividing the total science and technology program into "core vs. problem-driven" categories is difficult and it is not as easily done as it is in other scientific areas (e.g., medicine). However, simple indices based on the aggregate resources that support ORD's part of Agency Goal 8 (largely "core"), versus Agency Goals 1 through 7 (largely "problem-driven"), show a reasonably even split between "core" and "problem-driven" research. The Panel recommends that the Agency more clearly identify both ORD and Program Office science and technology efforts that it categorizes as "core" research. The Panel recommends that one or more program offices, possibly with SAB or other external reviewer participation, undertake a review of the process that starts at the beginning of the science development effort, and follows the evolution of the science investments to meet specific strategic goals in the context of core and problem-driven research.
- h) The Panel believes that it is important for EPA to extend its definition of "core" research to incorporate the concept of research areas in which EPA must exercise leadership. Without such leadership, it is unlikely that others will see the need to conduct sufficient research efforts in these areas to provide the information that EPA needs to support its decision making. "Core" research can also be thought of as those areas in which EPA has identified its role in relation to others who conduct research into other, and related, aspects of complex scientific and technological issues.
- i) The Panel believes that the EPA ORD research program addresses, categorically, most of the important issues needed to meet EPA's strategic objectives. Even though the transparency of EPA's science and technology program budget materials continues to improve, there is still much that is needed to provide insight to the Panel on program details that will allow it to consider the depth of EPA programs in specific research areas and to identify important efforts that are not being pursued. The Panel believes that the new five-goal strategic plan structure that EPA is now developing will help to clarify the extent of the science and technology investment, and its nature, that exists to support EPA's mission.
- j) The Panel noted some promising trends in the science and technology program. New areas are being explored (e.g., computational toxicology, Clear Skies) and a few traditional areas that have eroded over time are being reinvigorated (e.g., IRIS). There is also evidence of movement of efforts from core research areas to the more applied areas.

- k) The Panel believes that some areas of science are not being adequately addressed. These include certain issues where EPA is only one of a group of agencies that have responsibilities for an issue (e.g., asthma, childhood cancer), anticipatory research on health and environmental problems (e.g., use of suspect source waters), and research to address issues that have no clear legislative mandate (e.g., indoor air). For the first category, EPA should identify the important environmental role it seeks to play in the area and then work to build a research presence around this component. For the second type, the agency should develop a research presence on forward-looking complex exposures that are potentially associated with environmental and health risks. For the third type, "orphan risks," EPA should also develop a research presence because of their significant effects on overall human health.
- l) The Panel notes that there are also some important areas that the Agency has not been able to attend to in a significant manner (e.g., decision-making research, impaired drinking water sources).
- m) Several activities undertaken by the Agency can help in clarifying the importance of science in their programs and also would facilitate the review of the EPA science and technology budget. The Panel commends EPA ORD for developing its Program Design/Evaluation Logic Model; a model that provides a framework for linking science and technology programs to EPA's goals and strategic objectives and that also shows the link with performance measurement. Multi-Year Plans are also an important link in understanding EPA science programs and how they relate to goals, objectives and the achievement of outcomes.
- n) The Agency should explicitly consider the multi-utility of its existing and its new science programs. An important example of leveraging is demonstrated by considering how these existing, traditional programs (e.g., evaluating waterborne disease) can link to and synergize with emerging programs (e.g., Homeland Security).
- o) The Agency should continue to conduct research that will allow it to better understand the linkage between various human health and environmental interactions with environmental agents and identify ways in which these linkages can be used in performance measurement.
- p) The Agency should identify how its collaborative efforts with other Federal and private partners contribute to achieving important environmental outcomes.

The SAB, as it has in the past, again notes that it is difficult to definitively advise the agency on the adequacy and focus of its science and technology budget within the context of a quick turn-around review that is informed by traditional budget documents and supplemented by a series of additional explanatory Agency analyses that are developed late in the review process. This approach does not present a clear and complete picture of the content of EPA's science and technology program in support of the Agency mission. Therefore, in its budget review the Board inevitably finds itself in a position of providing other than full answers in response to the charge of the Agency.

During last year's science and technology budget review, the Board noted its intention to engage in more intensive and extensive evaluations of EPA's science and technology efforts so that it can provide advice to you, and to the Congress, that is more to the point of how EPA ensures the effective and efficient development of the science and technology information necessary to support the achievement of EPA's mission and how adequate the budget for a specific year is in focusing on important efforts, and in providing sufficient resources to ensure Agency success. Towards that end, we will work with Dr. Gilman, Assistant Administrator for Research and Development, and the Agency Science Advisor, as well as other EPA program offices that have science and technology programs, to develop a more effective and efficient mechanism for evaluating Agency science, and the budget for conducting that science. We will soon contact Dr. Gilman to initiate a new approach to performing this important SAB function.

We appreciate the opportunity to review, and provide you with advice on, the Science and Technology component of the FY 2004 President's Budget for EPA. The Board would be pleased to expand on any of the findings described in this report and we look forward to your response.

In closing, the SAB recognizes the increasing responsibilities that EPA faces and the increasingly complex nature of the issues that must be understood to meet these responsibilities. As we have stated in the past, the understanding and knowledge of these issues cannot be achieved without increased resources devoted to EPA's science and technology efforts. The SAB urges the Agency to clearly explain these needs to those in the Administration and the Congress who can influence resource allocations across government.

Sincerely

/Signed/

/Signed/

Dr. William H. Glaze, Chair EPA Science Advisory Board Dr. Genevieve Matanoski, Chair Science and Technology Review Panel EPA Science Advisory Board

NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board, a public advisory committee providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use.

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ABSTRACT

The Science and Technology Review Panel (STRP) of the US EPA Science Advisory Board (SAB) met on February 24 and 25, 2003, and again on March 21, 2003, to review the Science and Technology portion of the FY 2004 President's Budget Request for the U.S. Environmental Protection Agency. The Panel noted that EPA and ORD continue to be guided in planning their science and technology activities by Strategic Plans, Research Strategies and Multi-Year Plans and that the Agency continues to make progress in its use of internal and external collaboration in planning and implementing EPA's science and technology programs.

The Panel noted their continuing concerns with the downward trend in science and technology funding for EPA, in real dollar terms. The Panel suggested that the agency increase funding to its science and technology activities and recommended that Congress add funds to EPA's appropriation when it adds projects to that program. The Panel believed that the overall distribution of Agency science and technology resources by Goal was appropriate. The Panel was pleased that the STAR Fellowships program was restored in the FY 2003 Enacted Budget and recommends that the FY 2004 Fellowships be restored to the fully funded level of the 2003 Enacted budget. Further, the Panel suggested that the Agency consider further increasing all the STAR program components in the future.

The Panel observed a lack of consistency between the way ORD and the Program Offices report on which parts of their science and technology efforts are parts of "core" research and which are parts of "problem-driven" research. The Panel recommended that the Agency more clearly identify both ORD and Program Office science and technology efforts that it categorizes as "core" research. Further, the Panel noted the importance of thinking of EPA's "core" research in terms of that research in which EPA must exercise leadership in order for there to be sufficient science information to support Agency decision-making.

The Panel noted that the EPA ORD research program addresses most of the important issues needed to meet EPA's strategic objectives. However, they noted concerns with the continued lack of transparency in EPA's budget materials that explain the science and technology programs. The Panel noted that the new five-goal strategic plan structure that EPA is developing will help clarify the extent of the science and technology investment, and its nature, that exists to support EPA's pursuit of its mission.

The Panel considered the Multi-Year Planning process and the further development of the Science Inventory to be efforts that will contribute to the transparency of EPA's science and technology efforts. Other helpful activities include the development of EPA ORD's Program Design/Evaluation Logic Model that provides an intellectual framework for linking EPA science and technology programs to EPA's goals, strategic objectives, and performance measurement.

The Panel noted some specific areas that show promising trends in the Agency's

programs, some areas where the adequacy of efforts is not certain, and some important areas that the Agency has not been able to attend to in a significant manner.

The Panel recognized the increasing responsibilities that EPA faces and the increasingly complex nature of the issues that must be understood to meet these responsibilities. The Panel noted that the understanding and knowledge of these issues cannot be achieved without increased resources devoted to EPA's science and technology efforts. The Panel urged the Agency to clearly explain these needs to those in the Administration and the Congress who can influence resource allocations across government.

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- * Members of this SAB Panel consist of:
- a. SAB Members: Experts appointed by the Administrator to serve on one of the SAB Standing Committees.

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REVIEW OF THE FY 2004 SCIENCE AND TECHNOLOGY BUDGET REQUEST FOR THE U.S. ENVIRONMENTAL PROTECTION AGENCY: AN EPA SCIENCE ADVISORY BOARD REPORT

1. INTRODUCTION

1.1 Background

The EPA Science Advisory Board (SAB) was asked by the Office of the Chief Financial Officer (OCFO) (USEPA OCFO, 2002) to review the FY 2004 President's Budget Request for EPA'S science and technology program. This review was announced in the *Federal Register* on December 31, 2002 (USEPA SAB, 2002). The review was conducted by the Science and Technology Review Panel (STRP, the Panel), a panel which is predominantly comprised of members of the EPA SAB Research Strategies Advisory Committee (RSAC). The panel was further supplemented by other EPA Administrator-appointed members of the SAB to add to the disciplinary coverage and balance of the group conducting the review.

The Office of Research and Development (ORD) is viewed as the lead science office at EPA; however, a significant portion of the science conducted by EPA is not performed by ORD. Much of the science activities, managed and/or conducted by ORD, are appropriately categorized as research. In the Panel's view, science is a broader term that also includes the use of research results in analyses that support the development of environmental policies and regulations and each of the Program Offices and Regions conduct scientific activities that range from risk assessments to laboratory analyses. They are, therefore, participants in EPA's science and technology program. To ensure that the science conducted at EPA is well planned, organized, and coordinated, EPA has requested (since the FY 1999 budget proposal) that the SAB review the entire EPA Science and Technology budget. Prior to that time, the Research Strategies Advisory Committee had conducted an annual review of the Office of Research and Development's R&D budget request. This annual review helps the Agency with its science planning and in its evaluation of the effectiveness of the science budget under the Government Performance and Results Act (GPRA).

1.2 Charge to the Science Advisory Board

The charge to the Science Advisory Board asked the following:

<u>Charge Question 1</u>: Does the budget request reflect priorities identified in the EPA and ORD Strategic Plans?

<u>Charge question 2</u>: Does the budget request reflect coordination between ORD and the Program Offices, including identification of the science needed to support major upcoming rules and decisions?

<u>Charge question 3</u>: Does the President's Budget request provide adequate balance and attention to the core and problem driven research needed to provide satisfactory knowledge for current and future decisions EPA will be required to make?

<u>Charge Question 4</u>: Is the EPA research and development program addressing the important issues needed to meet EPA's strategic objectives and protect human health and the environment in the US and globally? What important issues are not receiving adequate attention at the requested level of resources provided for the R & D program and the S&T budget?

<u>Question 5</u>: How can EPA better use measures of performance that focus on environmental outcomes to identify the impact of its research and development program and the funds that Congress provides for that program?

1.3 Format of this Report

Following this Introduction, the report provides specific responses to the questions contained in the Agency's Charge to the Panel (Chapter 2).

2. RESPONSE TO THE CHARGE

In this chapter, the SAB Science and Technology Review Panel (STRP) provides its responses to the five charge questions that were asked by the Agency. The questions focused on whether the budget request: a) addressed Agency priorities; b) reflected the coordination of science activities and research across EPA and outside EPA; c) demonstrated an appropriate balance between core and problem-driven research; and d) focused on important environmental issues, or whether any such issues were missed. The charge also asked whether EPA could improve its research and development performance measures.

The Board's review of the EPA Science and Technology Budget request is always difficult. Among the issues that are faced in conducting the review is the short time available from the Panel member's receipt of the budget information until the time when they must report to the Administrator. This interval usually extends from the first week of February, when the budget and supporting materials are delivered to the Congress and released to the public (including the SAB), until mid- to late-April. Therefore, all the supplementary materials needed by the SAB to conduct its review must be prepared, delivered, evaluated, and deliberated upon quickly. The SAB's advice must then be developed in the form of a final SAB Executive Committee-approved report. Usually, this means that some of the materials necessary for informing the SAB members about the program details that are covered by the budget request may not always be available on time.

The Science Advisory Board will evaluate its review practices for the EPA science and technology budget components and propose ways in which this evaluation can be accomplished and more targeted advice can be provided to the Administrator and the Congress. Development of a new review approach is even more appropriate given the Agency's current actions to develop a revised Strategic Plan having a five-goal structure and the increasing emphasis, by those persons who are responsible for the budget processes, on demonstrating how science and technology budget components respond to national priorities and meet certain research and development evaluation criteria. Once the SAB's evaluation is complete, we will notify the Agency prior to next year's budget review of the types of information that will be needed by the SAB to support its review; and the best formats and approaches for presenting that information.

2.1. Strategic Priorities and the Budget Request

<u>Charge Question 1</u>: Does the budget request reflect priorities identified in the EPA and ORD Strategic Plans?

Yes, the budget request generally reflects the goals and priorities identified in the EPA and ORD strategic plans. As in past years, it is difficult to address this charge question in detail with the information presented to the Panel. In addition, the question as phrased may miss the main point, and that is, can the EPA Science and Technology program, even if well-targeted to Agency priorities, achieve success as funded. A twenty-four year history of the EPA Office of

Research and Development's funding (USEPA, 2003) shows that ORD's total budget has ranged from \$306 million (FY 1985) to \$627 million (FY 2003 requested) in actual dollars. In constant 1987 dollars the range has been from a high of \$462 million (FY 1980 actual) to \$371 million (FY 2004 budget request). This funding level reflects a range of from nearly 7 percent to nearly 9 percent of EPA's total budget during that period (see Tables 1 and 2 and Figure 1) (USEPA, 2003, 2003a). As in the past, the Panel remains concerned about the Agency's ability to meet its strategic goals and objectives within the limitations of a level to declining science budget (in constant dollar terms). This is important, because the development of high quality science-based regulations is not possible without an adequate research base.

Table 1. Distribution of the EPA Science and Technology Appropriation Request by Office¹

Office	S&T Dollars in FY 2004 Request	Percent of FY 2004 S&T Dollars ²		
Office of Research and Development ³	\$561 million	76%		
Office of Air and Radiation	\$111 million	15%		
Office of Water	\$ 27 million	4%		
Office of Enforcement and Compliance Assurance	\$13 million	2%		
Office of Administration and Resource Management	\$ 10 million	2%		
Office of Prevention, Pesticides and Toxic Substances	\$ 5 million	1%		
Office of Environmental Information	\$ 4 million	1%		
TOTAL	\$731 million	-		

¹Total resources for EPA from FY 2002-2004 across all appropriations: 2002 Enacted, \$8.08 billion; 2003 Requested, \$7.62 billion; 2004 Requested, \$7.60 billion.

²Percentages are approximate and do not add to 100.

³The Office of Research and Development also receives resources from appropriations in addition to S&T. From FY 2002-2004 this provided additional funds as follows: 2002, \$38.4 million; 2003, \$112.7 million; 2004, \$46.2 million.

Table 2. Total Funding by Goal and S&T Resources by Goal and By EPA Program Office (Dollars in millions)

		ollars in mill				
GOAL/OFFICE	FY 2002	FY 2003	FY 2004	Delta FY	Percent	Percent
(Total Dollars FY 2004 Request and	Pending	President's	President's	2004 vs	of total	of S&T
2004 S&T Funds as a % of Total)	Enacted	Request	Request	FY2003	S&T	Delta
1: Clean Air (\$617.4; 8.1%)						
Air S&T	170.3	174.7	177.0	2.3	24.2%	3.7%
-ORD	98.1	93.3	94.0	0.7		
-OAR	72.2	81.4	83.0	1.6		
2: Clean and Safe Water						
(\$2952.5; 38.7%)						
Water S&T	193.2	113.3	135.0	21.7	18.5%	35.3%
-ORD	102.3	93.6	107.2	13.6		
-OW	90.9	19.7	27.7	8.0		
3: Safe Food (\$119.0; 1.6%)						
Food S&T	14.9	14.4	16.2	1.8	2.2%	2.9%
-ORD	11.4	10.8	12.0	1.2		
-OPPTS	3.5	3.6	4.2	0.6		
4: Preventing Pollution &						
Reducing Risk (\$346.3; 4.5%)						
PPRS S&T	24.7	27.8	27.9	0.1	3.8%	0.2%
-ORD	22.1	25.1	25.6	0.5		
-OAR	1.7	1.7	1.2	(0.5)		
-OPPTS	0.9	1.0	1.0	0.0		
5: Better Waste Management						
(\$1846.6; 24.2%)						
BWM S&T	21.9	15.5	20.3	4.8	2.8%	7.8%
-ORD	15.4	9.5	10.8	1.3		
-OAR	5.5	6.0	9.5	3.5		
6: Reduce Global Risks (\$263.8;						
3.5%)						
RGR S&T	48.6	38.8	38.8	0.0	5.3%	0.0%
-ORD	21.4	21.7	21.5	(0.2)		
-OAR	27.2	17.1	17.3	0.2		
7: Quality Envir. Information						
(\$228.3; 3.0%)						
QEI S&T	10.6	9.4	15.4	6.0	2.1%	9.8%
-ORD	5.4	5.4	11.2	5.8		
-OEI	5.2	4.0	4.1	0.1		
8: Sound Science (\$357.1; 4.7%)						
SS S&T	269.7	254.6	278.2	23.6	38.0%	38.4%
-ORD	269.7	254.6	278.2	23.6	30.070	JU.7/0
9: Deterrents and Compliance	207.1	23 1.0	276.2	25.0		
(\$430.6; 5.6%)						
DC S&T	10.9	11.3	12.6	1.3	1.7%	2.1%
-OE	10.9	11.3	12.6	1.3	1.//0	2.1/0
10: Effective Management (\$468.8;	10.7	11.3	12.0	1.3		
6.1%)						
EM S&T	23.6	10.2	10.2	0.0	1.4%	0.0%
11.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1					1.7/0	0.070
-OARM	23.6	10.2	10.2	0.0		

^{*}Base which ignores the Unallocated Agency Pension Fund increment.

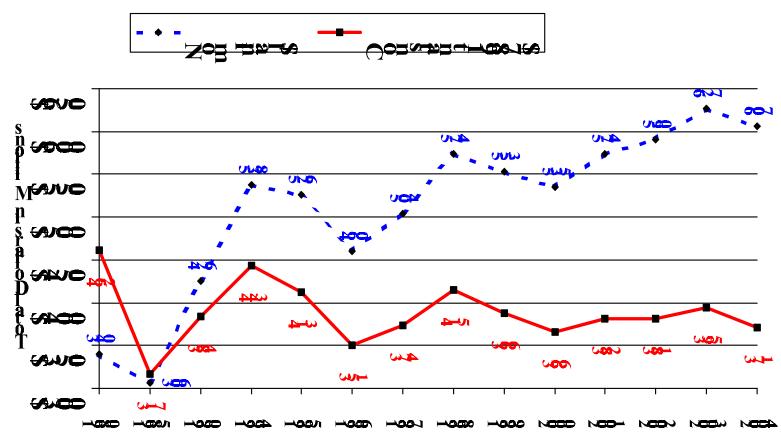


Figure 1. ORD Funding History from 1980 through FY 2004 President's Budget Request (after USEPA ORD, 2003)

The eroded science and technology funding is even more significant because of the increased complexity of current, and anticipated future, environmental and human health problems. For instance, many pressing environmental problems facing humans and ecosystems are not separate air or water media-specific problems, nor are they single chemical specific situations. Rather, they are system-wide issues related to impacts and effects from mixtures of contaminants and other environmental stressors at various levels. The effort needed to understand these issues is now greater. In addition, the Panel notes that there is a non-trivial investment of resources at EPA on infrastructure components that are critically important in ensuring that the Agency's science and technology efforts are coordinated inside and outside the Agency. This necessary investment further limits the availability of funds that can be applied directly to research on today's complex environmental problems.

EPA's science and technology efforts (S&T Appropriation) are conducted predominantly within an in-house EPA laboratory system that is managed by the Office of Research and Development. A smaller proportion of the science and technology effort is conducted by Program Offices other than ORD (see Table 2). A portion of the ORD science and technology program is conducted by outside organizations under ORD's extramural resources. The Panel believes that this three-component structure is important. ORD's management efforts have significantly increased the communication and coordination among these three components in recent years. Multi-Year Plans are an important part of this increased level of interaction.

The Science to Achieve Results (STAR) program is an EPA ORD grant program that funds high quality research proposals in response to a series of annual Agency solicitations. Proposals come from leading, independent environmental academic researchers and analysts around the United States. This program provides a mechanism by which the Agency can take advantage of concepts, capabilities, and facilities that exist in the scientific community outside of EPA. It can also ensure that there is a way in which the Agency can invest in innovative research that can supplement the efforts of EPA's internal programs. The results of this critical research program often move rapidly into use in direct support of EPA's environmental mission, both by Agency Headquarters and Regional Office components, and by the States. The importance of this peer-reviewed, competitive research grant program cannot be over emphasized, and the Panel is pleased to see that STAR funding is continued in the FY 2004 budget request. The Panel encourages EPA to consider increasing STAR funding in future years.

Another component of the STAR program annually awards Fellowships to university graduate students. In its report on the EPA FY 2003 Science and Technology budget (EPA SAB 2002a), the SAB expressed concern about the elimination of Fellowships funding. As the Board noted then, the STAR Fellowships have produced numerous valuable contributions to EPA science and the Fellowships are an important component of ORD's plans for developing, recruiting, and retaining a highly qualified and diverse workforce. The Panel is pleased that the FY 2003 Enacted Budget includes the restoration of the STAR Fellowships program at a level of \$9.75 million, and it strongly urges the continuation of this program in FY 2004 at its FY 2003 enacted level.

As in past years, the Panel strongly recommends that if Congress chooses to add specific projects or programs to EPA's science and technology program, Congress should also appropriate the funds needed for the successful completion of those projects and programs. Such actions by Congress will minimize the impacts on the scarce science and technology resources available for the study of increasingly complex environmental issues.

2.2 Coordination Between ORD and the Program Offices and use of Science to Support Rules

<u>Charge Question 2</u>: Does the budget request reflect coordination between ORD and the Program Offices, including identification of the science needed to support major upcoming rules and decisions?

Yes. The Panel was impressed with the continued progress made by EPA to heighten the level of interaction between ORD and the EPA Program Offices. The links between ORD and the Program Offices appear solid. These links advance the development of the scientific information needed to support regulatory programs and we encourage the Agency to ensure the continuation of this communication and coordination.

ORD research activities reflect the needs of the EPA Program Offices. The Agency has established a number of mechanisms that promote research in support of these needs. These mechanisms include the: a) development and implementation of Agency and ORD Strategic Plans - supplemented by the Multi-Year Planning (MYP) process; b) development of an ORD Program Design/Evaluation Logic Model; c) development and maintenance of the Science Inventory; d) proposal-development and review process under the Science to Achieve Results (STAR) extramural grants program; e) the use of agency wide science committees (e.g., Science Policy Council, Risk Assessment Forum); and f) external peer review and advice seeking processes which engage the National Academy of Sciences, the EPA Science Advisory Board, the ORD Board of Scientific Counselors, and *ad hoc* expert panels to provide input on the relevance of research strategies relative to agency decision-making. Figure 2, depicts EPA ORD's inclusive planning process that encourages such collaboration. This process reflects their Program Design/Evaluation Logic Model (see Figure 3).

Organization of interdisciplinary and interagency programs under National Program Directors continues to lead to structured and actively managed research programs in key areas (e.g., particulate matter, drinking water, global change, endocrine disrupting chemicals, genetically modified organisms, and ecosystem protection). Interaction between the National Program Directors and the Laboratory or Center Directors ensures that research programs receive attention at the highest level of management in ORD.

The ORD planning process to produce and update Multi-Year Plans is an effective means of communicating program needs to ORD and for ensuring that research strategies reflect critical program needs for scientific research and information. The Panel notes that not all of the 16 Multi-Year Plans have been peer reviewed and recommends that the peer review of the plans be

completed. The MYPs are key to ensuring that focused research is conducted in support of the Agency's strategic goals and that the research is coordinated across the Agency.

In past years, the SAB noted that the process by which research is planned is visible, but that it was difficult to obtain a clear view of how ORD's research plans were implemented within the laboratories. The Board previously expressed the hope that the Multi-Year Plans, when available, would show how the direction, of specific plans, shifts in response to research results, and how adjustments are made in the problem-driven portion of the research program in response to shifting Agency priorities. The development of Multi-Year Plans is a major step forward in linking research projects to the strategic goals of the Agency. MYPs also provide a mechanism for integrating research in support of basic science to the needs of program offices and to understanding how research in the laboratories relates to the EPA strategic goals. As a result, the process of demonstrating how research projects flow from Agency goals and are implemented at EPA laboratories is now more transparent (see Figure 4 for an example) and the Panel compliments the Agency on its progress in this area.

The Panel encourages ORD to continue to improve the mechanisms for establishing liaison with other federal agencies that work in the environmental arena. Evidence exists to demonstrate existing coordination of research between the EPA and other agencies. One example includes EPA's participation in the Committee on Environment and Natural Resources' (CENR) Air Quality Subcommittee which coordinates interagency research on particulate matter and on other chemicals represented by CENR subcommittees (or integrations of such subcommittees). The National Academy of Science's reviews of particulate matter research, and its role in promoting the integration of EPA research with that of the National Institute for Environmental Health Sciences, the Health Effects Institute and others, is a good model for oversight of research and interagency coordination. While costly, it has promoted the development of critical scientific information in support of an important regulatory initiative. The committee is aware of several other collaborations between EPA and other agencies – for example, review of ozone research through the North American Research Strategy for Tropospheric Ozone, participation in the National Toxicology Program, the Biosolids Program Inter-Agency Committee, coordination with the US Department of Agriculture and the Food and Drug Administration on issues related to genetically modified organisms, and the National Children's Study. There are additional collaborations with the Centers for Disease Control, the National Institute for Environmental Health Sciences, and the National Science Foundation. However, the extent of these interactions is not clear to the Panel. Many federal agencies are conducting research on issues relevant to EPA's mission and these activities could obviously benefit from and synergize with EPA's programs. Documentation of information on, and organization of, these interactions would help to ensure that they occur at levels that are most beneficial to EPA.

ORD's Inclusive Planning Process

Customer/User Needs

(OMB Criteria: Relevance)

- EPA Program Offices and Regions/States
- Federal research partners
- Private Sector

Multi-Year Plans

(utilizing the Program Design/Evaluation Logic Model)

Outside Peer Advice

(OMB Criteria: Quality and Relevance)

- Science Advisory Board
- •Board of Scientific Counselors
- · National Research Council
- NAPA
- Scientific Peer Reviews

EPA Strategic Plan

(OMB Criteria: Relevance and Performance)

Government Performance and Results Act Goals

- · Clean Air
- · Clean Water
- Safe Food
- Safe Communities
- Better Waste Management
- Global Risks
- Right to Know
- Sound Science

ORD Strategic Planning

(OMB Criteria: Relevance)

- ORD Strategic Plans
- Peer Reviewed Research Strategies and Plans

Figure 2. ORD's Inclusive Planning Process (after USEPA, 2003a, page 3)

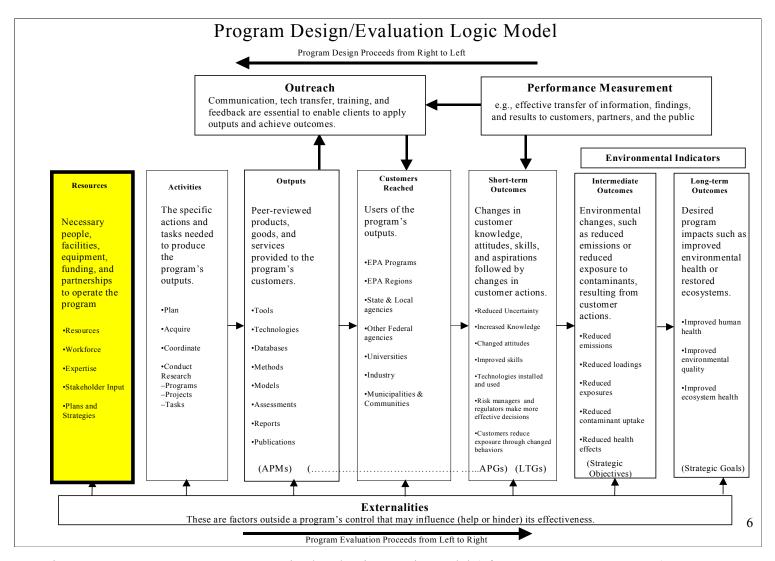


Figure 3. US EPA ORD Program Design/Evaluation Logic Model (after USEPA, 2003a, page 6)

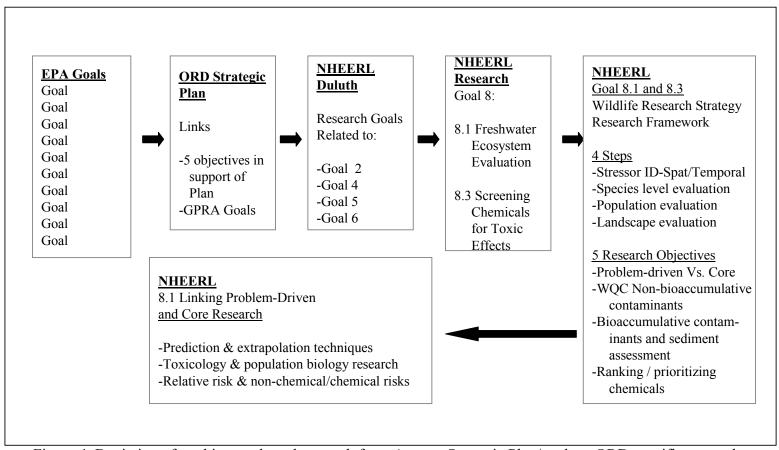


Figure 4. Depiction of tracking goals and research from Agency Strategic Plan/goals to ORD specific research projects using an example of research at the Duluth Laboratory.

The Panel encourages the Agency to interact with the National Cancer Institute on issues of mutual interest, for example, on the issues of fetal, infant, and childhood exposure and the later development of cancer in children and adults. This should help the Agency to leverage its research dollars and enhance its program on children's environmental health. Furthermore, ORD should continue to consider how to enhance its interactions with the States, the private sector, and public interest groups. Some groups have substantial research programs and expertise that would significantly complement EPA's efforts.

Agency rules should be supported by sound scientific reasoning and adequate scientific data, although, every research program does not necessarily need to be linked to a specific rule. Having a way to track these relationships is important. Even though the Panel did not receive information on Agency tracking mechanisms that ensure the existence of efforts to develop the science needed to support major rules and decisions, it did in the past, review the EPA Peer Review Manual and system. At that time, the SAB was introduced to the Science Inventory, a catalog of science activities and scientific/technical work products underway at the US EPA. At that time, the inventory was to track major research projects and identify whether the research effort was linked to a specific Goal and specific rule making. The Panel encourages the Agency to further develop this system so that it can ensure that the science needed to support each rule is peer reviewed as required by Agency guidelines. The Panel is pleased to learn that the Science Inventory is being updated and hopes that the updates will permit a clearer picture of how science activities link to specific Agency actions. The Panel looks forward to learning more about this issue and learning more about the updated inventory. Further, the Panel encourages the Agency to complete this project and make the inventory available to the public. Doing this would also complement the Agency's renewed focus on data quality and the development of scientific support for decision-making.

2.3 Balance Between Core and Problem-Driven Research

<u>Charge question 3</u>: Does the President's Budget request provide adequate balance and attention to the core and problem driven research needed to provide satisfactory knowledge for current and future decisions EPA will be required to make?

Again this year, the Panel was not able to clearly answer this question in the time available and with the information provided. ORD provided the Committee with documentation suggesting that their research efforts under Goal 8 of the Agency's Strategic Plan are mostly "core research." This documentation also indicated that ORD's efforts under Goals 1 through 7 of the Agency Strategic Plan are more appropriately categorized as "problem-driven research." Following this distribution, and using \$606.9 million as the base ORD FY2004 request, ORD allocates approximately 46% and 49% of the budget, respectively, to their "core" and "problem-driven" research areas. This year about 5% of the budget request is devoted to Homeland Security. As in past years, this allocation is reasonably consistent with the balance recommended by the National Academy of Sciences (NAS) and with ORD's Strategic Plan.

The Panel's review of the budget request materials did find ample evidence that the Agency recognizes the need to balance core and problem-driven research. For example, to supplement its review materials for the FY 2004 science and technology budget review, the Panel had available information on a number of ORD Research Strategies and plans (most were available from the ORD website). In addition, the SAB reviewed two Multi-Year Plans in the past – water quality and pollution prevention (EPA SAB, 2002b). In part, these reports reinforced the impression that the Agency is paying attention to the necessary interplay between "core" and "problem-driven" research. That being said, it is frequently difficult to draw a bright line in categorizing research projects into one category or the other based upon the Agency's program presentations or from the text of Multi-Year Plans and Research Strategy documents. For example, it is not possible to identify core and problem-driven research efforts in the Asthma Research Strategy. Because many of the MYPs have not been reviewed by the Panel, we cannot address the balance question in other areas. The Panel is somewhat concerned, however, that some of the observed balance seems artificial and contrived. For example, a great deal of new research for Clear Skies is included under Goal 8 (because it is a part of a multi-media mercury program) when it appears more suitable for Goal 1. The Panel was not convinced that this classification accurately reflects the nature of the science being conducted.

The Panel recognizes that it is difficult to imagine good "problem-driven" research that does not contribute in some way to the development of basic scientific principles in environmental science and technology. Conversely, it is difficult to imagine the pursuit of "problem-driven" research without the construction of concepts and development of capabilities that come frm a "core" research program. The Panel recommends that the Agency define the terms "core" and "problem-driven" research as they relate to the EPA science and technology programs. Further, the Agency should more clearly identify their "core" research programs and maintain the depth and diversity of expertise needed to achieve an effective science and technology program. It is especially important to develop the discipline in the program offices and ORD, to show the allocation of their S&T and non-S&T budgets meaningfully into the broad categories of "core" and "problem-driven" research for SAB budget reviews.

Through the framework of its Strategic Goals, the Agency is making progress in describing the decisions it needs to make, and the science needed, to inform Agency decisions. However, insufficient information was provided to allow the Panel to evaluate whether the FY 2004 budget request is adequate to support the research needed to satisfactorily inform the current and future decisions EPA will be required to make. With the exception of ORD, none of the program offices described their initiatives or investments in the context of "core" and "problem-driven" research, and all of the "Research" dollars listed in a supplementary resource table provided to the Panel by EPA's Office of the Chief Financial Officer (USEPA, 2003b) reflects only ORD activities. The document provided no information on "core" versus "problem-driven" research outside of ORD. This might suggest to a reader of the 2004 Budget Summary (USEPA, 2003c; USEPA2003d) that science and research are not important to these non-ORD programs. The Panel had hoped to find, based on past SAB recommendations, that all program offices would tie their key programs and total science and technology budgets not only to the Strategic Goals (information which is currently provided to the Panel), but also to the "core" and "problem-driven" research categories.

Moreover, information included in the Congressional Justification document (USEPA 2003e), that was reviewed by the Committee, did not provide additional details on "core" and "problem-driven" research. The Panel notes that each program made convincing presentations that they routinely invest in "problem-driven," and in many cases, "core" research areas. The key issue here is how to categorize the dollars and programs better so that the investments are clear in a review of the program budgets.

The classification of non-ORD program budgets and how they are reported may in fact be due to the science demands that the program offices face. Their overall strategic incentives do not lend themselves to do research that does not relate directly to supporting rules and their implementation, and thus, it could be a problem for those programs to label any of their dollars as "core" research. The Panel finds, however, that the inconsistency between the reported program data and the information necessary to answer this charge question suggests a fundamental need to rethink the definition, division and measurement of "core" and "problem-driven" research.

The Panel believes that better information about how resources are allocated between these two categories would be a first, and necessary, step in facilitating the review of the EPA science and technology budget. It would not, however, be the final step. A finding that, overall, program offices are striking a balance of some specific percentages, such as the 50%/50% NRC guideline, would not in itself indicate that this is the right balance. The Panel believes that the key programs and program offices in general need to consider what balances are appropriate to yield research useful for EPA's decision-making. A focused, deliberative process is necessary to meet this requirement. As a result, the Panel recommends that one or more program offices, possibly with SAB or other external participation, undertake an evaluation of their processes, starting at the beginning of the science development effort, and following the evolution of the science investments to meet specific strategic goals, in the context of "core" versus "problem-driven" research. This evaluation might be implemented at the program office or perhaps at the level of some candidate key programs. The intent of the evaluation would be to help direct the Agency to an appropriate, meaningful, and useful, classification framework that is related both to budget planning and consistency with EPA's mission and its role in science funding more generally. The Panel believes that this evaluation is particularly important now because of the pending change to an Agency Strategic Plan having five strategic goals, all of which explicitly discuss "sound science." This review could be carried out in association with the planning for revising the SAB budget review process.

In addition to issues about directing, classifying and tracking "core" and "problem-driven" research, the Panel continues to be concerned that EPA does not always appear to have "core" research programs in some areas where strong arguments could be made for EPA to develop "core" capabilities that anticipate the development of new science areas, or where it should continue "core" research as part of EPA's leadership role for specific Federal agency science activities.

During the FY 2004 budget review, the Panel identified the Agency's stated need to enhance its capabilities in computational toxicology as an example of an area where "core"

research should be pursued in order to enhance EPA "core" capabilities. The Panel endorses the new attention placed on this area. As described, the computational toxicology area would include new tools in molecular biology and bioinformatic approaches to toxicology as well as the older forms of computational toxicology, such as structure-activity relationships. These new approaches will become fundamental for identifying individuals in the population that could be more susceptible to environmental stressors. These new tools should provide the opportunity to expand the Agency's research on susceptible populations well beyond the traditional, simple categorization schemes (i.e. children's health, women's health) on which the Agency now depends. Because of the transforming influence that these advances can have on the Agency's regulatory programs, the Panel recommends that, the Agency's evaluation of the balance within their "core" research programs should include some consideration of developing EPA in-house capabilities to understand and effectively guide the activities linked to these new tools.

The Panel also considered examples of areas where EPA is the recognized leader in a science area and therefore must maintain their critical leadership role in "core" science. One such area is the sampling and analysis of air and water. This provides both the fundamental understanding of environmental systems that are necessary prerequisites for developing effective and efficient regulations, and determining compliance with established standards. As a leader in this area, EPA's "core" research can prevent deterioration in important EPA methods and help to maintain a vital and active science community.

Another leadership example is in the complex environmental problems that are associated with drinking water research. These problems may require innovative activities to develop appropriate controls. For example, chlorination of drinking water is a very complex issue. However, disinfection by-product research appears to retain a focus on the trihalomethanes and haloacetic acids. There continue to be questions about the true identity of disinfection byproducts that might cause the health effects that have been observed in certain drinking water epidemiologic studies. Further exploratory work is required to resolve this issue. Core research investments can help foster more aggressive and innovative analytical efforts to identify contaminants that are the probable causes for the cancer and putative reproductive effects that have been reported.

2.4. Strategic Issues

<u>Charge Question 4.</u> Is the EPA research and development program addressing the important issues needed to meet EPA's strategic objectives and protect human health and the environment in the US and globally? What important issues are not receiving adequate attention at the requested level of resources provided for the R&D program and the S&T budget?

The Panel is of the general opinion that the EPA ORD research program addresses, categorically, most of the important issues needed to meet the Agency's strategic objectives as outlined in the Agency's Strategic Plan. The Panel was gratified to see that research and development efforts have gained visibility in goals 1, 2 & 4. Panel members appreciate EPA's efforts to organize the research budget within the structure of EPA's strategic goals and believe

that such an organization of information improves program transparency, facilitates the analysis of the science and technology efforts across offices, and highlights the coordination among the offices. Even though the transparency of EPA's budget materials that explain Agency science and technology programs continues to improve, much more is needed to sufficiently improve program clarity so that the Panel can consider the depth of EPA programs within each strategic objective, and can identify important efforts that are not being pursued.

A briefing by Agency representatives on its new five-goal EPA strategic plan architecture (USEPA, 2002a), suggests that this new plan might offer some intrinsic advantages to those trying to understand the link between EPA's science and its strategic objectives, over the current Strategic Plan having ten-goals. Members of the Panel encourage EPA staff to continue their efforts to describe how investments in science and technology integrate with each of the Agency goals that are a part of its Strategic Plan. The new five-goal structure appears to have the potential for a clearer delineation of the major science and technology priorities in each EPA program and to explicitly provide a link between these priorities and Agency goals and budget allocations. In the current review, the written materials and the presentations did not provide such explicit links for a sizable portion of the S&T budget. These links are important for evaluating whether the investments are addressing important issues at appropriate dollar and staffing levels.

As noted in its response to Charge Question 1 above, the Panel remains very concerned with the flat to declining resource base for the Agency's research programs (see Figure 1). The Panel believes that the science and technology investment (S&T account) does not reflect the importance of research to the achievement of EPA's goals. Because of this, the SAB suggested, during its review of the FY 2003 budget request, that the research budget be increased within the Agency by 1% of the total Agency budget per year until adequate resources are invested in EPA science and technology. The Panel hastens to note, however, that this does not mean that transfer of funds from Agency regulatory programs will solve this problem. These programs already complement research activities through their own activities that are conducted under other appropriations (e.g. EPM). The panel is hopeful that the new goal structure being developed by the Agency will make it possible to more directly judge the science needs of the agency and the adequacy of science and technology budgets to address the needs in a timely fashion

The Panel observed some promising trends in the actual S&T budget account. There are some new investments in research in the FY 2004 President's budget for science and technology funding. While the Agency provided few specifics for some of these programs, there was a clear signal that ORD intends to make a substantial investment in computational toxicology [apparently about \$9M and 17 full time equivalents (FTE) that includes nearly \$4M in new resources as well as realigning some ongoing, but related activities within ORD]. ORD is proposing to couple computational methods with advances in genomics to enhance the Agency's ability to develop new ways of identifying problem chemicals and to deal with complex environmental problems. An initiative in this area was suggested during SAB budget reviews in prior fiscal years. The Panel is supportive of this initiative and believes that it will be invaluable to the Agency program offices as they begin to address more complex environmental problems

in the future. The consolidation of resources already available within ORD appeared to come from programs that would also benefit from the initiative (e.g. the Endocrine Disrupting Chemicals research program).

The Panel was also pleased to see that the Agency has allocated additional resources (\$5.2 M & 19FTE) to modernizing and updating the Integrated Risk Information System (IRIS). This system is used as extensively outside the Agency as it is within EPA because it provides consensus interpretations on the available science about specific pollutants. Unfortunately, IRIS has fallen behind the times because the past resource base was not sufficient to maintain it. The Panel sees this as a very critical function within the Office of Research and Development.

Another activity of importance is the Clear Skies Initiative (a \$6.5M commitment), which the Panel endorses. The identification of the portion of this activity that is to fall under the purview of ORD appears odd since it constitutes an admitted concern for the air program but focuses on a single contaminant, mercury. The research appears to be directed entirely to control and measurement technologies and modeling activities that seem very pragmatic and goal oriented. In the briefings to the Panel, Agency representatives indicated that this placement reflects that this initiative is seen as part of a broader multimedia effort by ORD on mercury in the environment.

It was encouraging to note a modest trend in the transition of some research from the "core" research program (e.g., Goal 8) to the more "problem-driven" research housed under Agency media-specific goals. For example, the transfer of \$323 K and 3.1 FTE for ecosystem protection to research efforts under Goal 2 and \$183 K and 1.8 FTE to research on pharmaceuticals and personal care products, provides some evidence of such a change and indicates that the research has progressed to the point that it can be used to support mission-specific decision making by the program offices.

Despite these positive signs, it is the Panel's opinion that the Agency needs to think more strategically about its research program. Concerns identified by the Panel fall into the following three groups and are elaborated upon in examples provided below in the text.

- a) Cases where there is a significant level of research going on in other Federal agencies, but where there is a need to identify and mitigate environmental contributors to the disease.
- b) Research that should be directed at anticipating health or environmental problems that will arise in the future.
- c) Research that is needed to more thoroughly address important identified sources of environmental exposure for which there is no clear legislative mandate for regulation (orphan risks).

The Office of Air and Radiation presentation to the Panel indicated that asthma was a science priority. Research to address this priority was not explicitly identified as a key program. Apparently, this research is funded under "indoor environments." Panel members found that it

was not possible to judge whether the level of funding in this area is adequate or not. It is obvious that EPA cannot undertake a major scientific program that would encompass all possible areas of research on asthma. Moreover, many other agencies are already involved in extensive research endeavors on this disease, and these Agencies have substantially greater resources than EPA. The Panel recommends that EPA identify the areas in which it can play a unique role, for example, a focus on identification and measurement of the important environmental variables that might contribute to this disease. The budget and research aims discussion should then identify the methods and steps EPA will take to bring their scientific work to the table in cooperation and partnership with other agencies' efforts to control this disease. One area where the Agency may be able to make a unique contribution is in the improved characterization of the contribution of ambient particulate matter (PM) to indoor air pollution, an activity that seems to have been sacrificed in realigning some of the science and technology resources mentioned earlier.

Another example of the first concern is the obvious need for the Agency to identify populations that are susceptible, or sensitive, to environmental exposures. The Agency appropriately identified children as a population that is especially susceptible to certain environmental agents. The Agency should recognize that very large programs in childhood diseases are housed in other Federal agencies, and EPA should consider those areas of environmental importance that are not being addressed by those programs, and develop a structured program to address the issues. Based upon information provided, the Panel suspects that the resources allocated to this area are insufficient, but no specific strategy was provided that would now allow a better evaluation leading to specific recommendations.

It is more difficult to provide specific examples of the second concern, that is, anticipating risks in the future. This work is either delayed, or simply not anticipated, because of existing program emphasis on current regulatory problems. A simple example might be the pressure that increasing population density exerts on the demand for water. As the supply becomes increasingly scarce, demand will drive populations to use water supplies from suspect sources. The Agency must begin to develop programs that identify forward-looking methods for evaluating the complex exposures and the potential health risks that may arise from this situation. An important issue will be to identify what constitutes an acceptable water supply and what mitigation strategies will be necessary to make impaired waters suitable for consumption.

The Panel noted that when a legislative mandate is absent, there are "orphan" risks (even known risks) that seem not to be sufficiently addressed in the budget process. One such area involves hazardous constituents in indoor air. These risks are judged by scientists working in this arena to be greater than those posed by many emissions from point, area, and mobile sources. Yet research to reduce residual uncertainties and risks from indoor air pollutants, or to devise intervention strategies in this area, receive relatively little attention in the research budget. While EPA has no statutory authority to regulate indoor air quality, research in this area is necessary to achieve the ultimate goal of reducing exposures and the health risks resulting from exposure to airborne contaminants.

The Panel believes that the issues falling into the three categories discussed above should be a significant component of the "core" research activity of the Agency. The Office of Research and Development should be taking a leadership role in these areas.

With essentially flat funding levels for science, allocating resources to one area frequently means that research on other issues will be reduced or eliminated. It is important to assess whether these transfers will seriously impair the research in a priority area. Examples include:

- a) Portions of the pharmaceutical and personal products program resources under Goal 8 (total of \$710K) appear to have been transferred to Goal 7 to support assessments within the Integrated Risk Information System (IRIS program) and to the biosolids program in Goal 2. It is not clear whether these two activities will address the major issues related to the appearance of these types of compounds in municipal wastewater. Thus, the Panel questions whether the Agency has sufficient resources focused on the potential contamination of drinking water by these contaminants which appear to be ubiquitous in municipal wastewaters and runoff water from consolidated animal feeding operations (CAFO) operations.
- b) The shift in resources (\$1.8M enhancement) from several activities of the Agency to research on determining and reducing health risks from the production and application of treated wastewater sludge for land application as fertilizer appears to be sound. The Panel is concerned, however, that some areas of focus of the previous programs are going to be lost. For example, the issues related to CAFO operations are not restricted to the problems of disposing of animal waste, but raise issues of microbial and endocrine disruptor contamination of the surface water that drains these sites.
- c) The Agency has redirected research in the water programs to address its new responsibilities for water security under the Homeland Security program. This effort has primarily impacted Contaminant Candidate List research on lower priority pathogens (fungi and protozoa). In addition, the shift in water program resources to the objective of obtaining longitudinal and dietary consumption information in support of the food quality protection activity and to support enhancement of the IRIS system appears to have led to the elimination of research to examine attenuation of viruses in watersheds, which is an important area of research. In addition, research on the mitigation of N-nitroso-N-dimethyamine (NDMA) in water distribution systems appears to be eliminated. The Agency should not abandon research into analytic methods for nitrosamine chemical by-products of chlorination and chloramination. This research is needed to evaluate the extent of this potential problem. Nitrosamine contamination of drinking water is one plausible explanation for the bladder cancer risk attributed to chlorinated water.

In addition to these particular efforts, the Panel notes that there are several recognized environmental problems that simply do not seem to receive significant attention in the science and technology budget request. Specific research or investment areas in this category include:

- a) Decision making research. Decision-making research does not appear targeted to the internal EPA decision-making process related to specific investments in the science programs of the Agency. ORD should consider that research in this area may improve decisions on resource allocations within its research programs.
- b) Susceptible/sensitive populations. The Agency identifies susceptible populations, and in particular children, as a major population that needs increased study. The Panel simply questions whether the resources allocated to the concerns of susceptible and sensitive populations is sufficient given its obvious importance to the regulatory programs of the agency.
- c) Sediment assessment of contaminants and improving water quality criteria methodology through development of bioavailability models and assessment of dietary exposure.
- d) Drinking water from impaired sources is becoming an increasingly complex problem. Drinking water standards are developed with the explicit assumption of an acceptable source. For this reason drinking water standards have not been regarded as sufficiently protective when drinking water is drawn from sources heavily impacted by intensive agricultural practices or municipal wastewater. In part, this is because important contaminants in these sources often do not conform to expectations. Such contaminants can range from novel precursors of disinfection by-products to hormonally active compounds and pharmaceuticals.

2.5. Performance Measures

<u>Charge Question 5</u>: How can EPA better use measures of performance that focus on environmental outcomes to identify the impact of its research and development program and the funds that Congress provides for that program?

The Panel is pleased that the Agency has started to make progress in developing a framework for linking the impact of its research program to specific gains in public health and environmental quality. The SAB addressed the question of environmental outcomes as part of its review of two Multi-Year Plans. The Agency has responded commendably to past SAB recommendations on the need to clearly define the characteristics of performance measures that can be used to monitor the impact of its actions on human health and the environment. EPA's beginning efforts to develop research to allow it to evaluate the public health outcomes from risk management actions provides evidence that the Agency will be addressing this issue strategically over the next five to ten years.

The implementation of Multi-Year Plans (MYP) for Agency research is a significant improvement over past practices. MYP implementation provides the opportunity for a more strategic use of research in characterizing the nation's critical environmental and human health risks and the development of cost-effective risk management options. The utility of any strategic research program must be defined in terms of its final objectives. In EPA's case, the final objective is the improvement of environmental and/or human health indices by implementing

regulatory efforts that are supported by Agency science programs, and the effective prevention of environmental degradation or the introduction of new potentially hazardous agents that could injure human health and/or the environment.

The Panel recognizes the difficulty inherent in evaluating Agency research programs in terms of measures of their contribution to the ultimate goal of improving the environment and human health. In some cases, Agency programs are designed to contribute to improving human health and environmental conditions that are already in a degraded state (e.g., hazardous waste and Superfund cleanups). In other cases programs are designed to prevent risks (e.g., pesticide use registration reviews and toxic substances pre-manufacturing review). In both cases, such evaluations could even produce misleading results because such outcomes are influenced by factors external to USEPA research and regulatory programs, or the outcome of interest may have a very long latency period. In such cases, useable outcomes may need to be defined in terms of achieving a series of intermediate goals that are increasingly proximal to the final objective (e.g., achieving and demonstrating a reduction in exposure to a chemical through risk management decisions as opposed to demonstrating a reduction in the incidence of a disease that might be linked to the exposure).

The Panel commends the Agency for its recent and continuing efforts to develop the Program Design/Evaluation Logic Model that is relevant to evaluating the outcomes from Agency science and technology efforts (see Figure 3 above). Some of the performance goals and measures incorporated into the model could be used as intermediate outcome measures to demonstrate the impact of EPA's research efforts. However, and as the SAB has stated in past reviews, to ensure accountability, the Agency needs to clearly define the characteristics of such measures and also to incorporate development of suitable outcomes as part of the research planning effort. Additionally, the Panel suggests that the Agency use its "Program Design/Evaluation Logic" model to review specific risk characterization and risk management issues that the research program was designed to address, and to determine the extent to which the research program has enhanced the ability within and outside the Agency to address its global (higher-scale, ultimate) goals.

In some cases, regulations, policies and technical guidance have been developed on the basis of assumptions or incomplete information. The Agency's research program can be used post-implementation, to evaluate or revise previous actions on environmental issues. An example of this process is the Agency's new regulation on particulate matter (PM) that is based on epidemiological studies that have demonstrated associations between ambient PM10 levels that were within the older standard and increases in daily cardiovascular and respiratory mortality. The Agency engaged in an intensive research program on PM. The risk management decision to change the standard to PM2.5 was based on the reasonable assumption that particles smaller than PM10 are more likely to result in adverse health outcomes. It is possible to design a research program that collects ambient PM2.5 concentration data in a manner that is amenable for use in similarly designed epidemiological studies in order to evaluate the impact from the earlier risk management decision. EPA could use these proximate goals (e.g., yearly reductions in ambient PM2.5 concentrations) as performance measures while enough data are being collected to revisit the epidemiological basis for the original risk management decision.

The use of environmental and human health indicators to evaluate research programs or risk management actions presents significant scientific challenges. Primary among these challenges is the establishment of the causal links between the products of the programs and measurable indices of environmental and human health conditions. Some impacts may not be discernable within the time frame of reference. The Agency needs to devote resources to research in this area with the intention of developing appropriate evaluation criteria for research on the outcomes of risk management decision-making. The Panel commends the Agency, for its recent initiative to develop a State of the Environment Report. The Panel recommends that appropriate research be performed to support this new initiative. Beyond the research program, the Agency's efforts to demonstrate the utility of its programs toward satisfaction of Government Performance and Results Act (GPRA) goals will benefit from this type of research. Similar recommendations were made as part of the SAB's review of 1996 Risk Management Planning for Wet Weather Flows (EPA SAB, 1999).

In the budget documents, the performance measures that are listed represent mostly products, not clearly correlated with achieving the outcomes that are expressed as targeted percentage improvements in the quality of environmental media and human health. Some of these performance measures are questionable (e.g., a 2% reduction of air toxics from stationary and mobile sources over the 1993 baseline is well within the error of emission estimates). As in past years, it is not clear how this year's budget request builds upon previous years' research output and represents a march towards achieving the targeted improvements. It is also not apparent that resources have been allocated for research on outcomes.

While the Agency is interacting increasingly with other agencies, it is not clear how research from external sources is incorporated into the Agency's science planning process. More specifically, it is not apparent that pertinent research and data from other agencies are considered as sources of outcome measures that could be used to monitor the impact from EPA's regulatory decision making. The issue of using suitable research from other Agencies is also important because reviews of external programs and engagement of others who work on issues that may be related to Agency projects present opportunities to leverage resources and develop the synergies that are needed to effect positive change. The Panel recommends that the use of inter-agency research be clearly communicated, including how external information is factored into the Agency's research planning effort, and how relevant results from this research are being considered as potentially useful outcome measures.

In its budget activity, the Agency should recognize and identify the potential impacts of specific projects that have multiple utility across EPA and other government programs. For example, a significant proportion of EPA's more traditional research portfolio has direct application to new issues such as Homeland Security. A specific example is the Agency's research program on water-borne infectious diseases that has a direct application to the recently initiated Water Security Program.

Another example of a multi-utility Agency research program is EPA's research program on the health effects of particulate matter (PM). Two of the key issues traditionally targeted by

that program are determining the fraction of outdoor particles that can penetrate indoors and affect exposure, as well as the structural and ventilation characteristics that can affect such penetration in buildings. It is obvious that the same questions are directly relevant to the issue of protection of the public from exposure to biological agents in airborne particulates that are of interest in Homeland Security. Thus, collaboration between EPA and the new Department of Homeland Security could help accelerate research directed at investigating if and which outdoor particles penetrate indoors and contribute to exposure in environments where the general population spends over 90% of their time. An additional utility of such collaboration is that it could provide information on what sizes and the extent to which biological agents in particle form could penetrate indoors. New programs can benefit from synergies that can derive from input from related research agendas. The panel recommends that the Agency consider the cross-cutting impacts of projects in its continuing efforts to develop a system for measuring outcomes from its research programs and projects.

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APPENDIX A – ACRONYMS

CAFO Consolidated Animal Feeding Operations

CCL Contaminant Candidate List

CENR Committee on Environment and Natural Resources

EMP Environmental Management Program EPA US Environmental Protection Agency

FTE Full-Time Equivalents

FY Fiscal Year

GPRA Government Performance and Results Act

IRIS Integrated Risk Information System

K ThousandsM Millions

MYP Multi-Year Plans

NAS National Academy of Sciences NDMA N-nitroso-N-dimethylamine

NHEERL National Health and Environmental Effects Research Laboratory

OAR Office of Air and Radiation

OARM Office of Administration and Resource Management

OCFO Office of the Chief Financial Officer
OEI Office of Environmental Information

OPPTS Office of Prevention, Pesticides and Toxic Substances

ORD Office of Research and Development

OSWER Office of Solid Waste and Emergency Response

OW Office of Water PM Particulate Matter

RSAC Research Strategies Advisory Committee

SAB Science Advisory Board STAR Science to Achieve Results

STRP Science and Technology Review Panel

S&T Science and Technology WQC Water Quality Criteria

APPENDIX B – BIOGRAPHICAL SKETCHES

1. Introductory Note

The persons below have been selected from among the US Environmental Protection Agency's Science Advisory Board membership to be participants on the panel that will review the EPA's FY 2004 Science and Technology Budget. The charge questions that the panel will respond to are posted on this website as well. The panel membership was drawn largely from the EPA SAB's Research Strategies Advisory Committee, a committee primarily established to review the EPA Science and Technology Budget. Additional Panel members were drawn from the SAB membership to fill in missing expertise and to add additional perspectives to the Panel. As noted in 67 FR 79912 (December 31, 2002) this list was posted to solicit public comments on the members. Comments were taken until January 21, 2003.

2. Panelists

CHAIR

Dr. Genevieve Matanoski

Dr. Matanoski is a Professor of Epidemiology at the Johns Hopkins University School of Hygiene and Public Health in Baltimore, MD. For a time after medical school she pursued a career in pediatrics and general preventive medicine. After earning a Doctor of Public Health Degree, she was appointed to the faculty of Johns Hopkins University and has been a professor since 1976. In addition to teaching and research, Dr. Matanoski has had appointments in a number of teaching and training programs in the U.S. and abroad and is a frequent advisor to legislative and policy-making groups. She is a member of several scientific advisory bodies both for governmental agencies and for industry. She is a past Chair of the EPA Science Advisory Board, as well as a past Chair of the SAB Radiation Advisory Committee. She now serves as Chair of the Committee. During her tenure on the EPA SAB, Dr. Matanoski was involved in the writing of several documents produced by the SAB to provide advice to EPA including the "Beyond the Horizon: Using Foresight to Protect the Environmental Future" document and the Integrated Risk Project report "Toward Integrated Environmental Decision-making," and was Chair of the latter Committee. She is the author or co-author of over 80 publications.

Dr. Matanoski's work has focused on the epidemiology of cancer, including bladder, lung, skin and uterine cancers, and leukemia. Her research studies have examined the risks associated with occupational and environmental exposures to such agents as radiation, electromagnetic fields, and chemical substances as styrene, butadiene, arsenic and environmental tobacco smoke. Recent research has emphasized reproductive effects and congenital malformations from environmental exposures. Her early work involved infectious diseases and illnesses in infants and children. Dr. Matanoski received a BA degree in chemistry at Radcliffe College and a MD at the Johns Hopkins School of Medicine. She also earned a Doctor of Public Health Degree from the Johns Hopkins University School of Hygiene and Public Health.

MEMBERS

Dr. William Adams

Dr. Adams is currently Principal Environmental Scientist for Rio Tinto. He was previously Director of Environmental Science for six years at Kennecott Utah Copper, Salt Lake City, Utah. Dr. Adams responsibilities include managing product stewardship programs, environmental research, ecological risk assessments and interface with regulators on science-based issues. Recent research interests include developing ecotoxicology risk assessment methods for metals, site-specific methodologies for water quality criteria for metals, and development of an alternative strategy for metals to replace the existing PBT (persistent, toxicity and bioaccumulation) approach. Dr. Adams has published several papers on methods for assessing sediments and was instrumental in developing the science supporting equilibrium partitioning theory (EqP) for non-polar organic substances. He has also published several papers in the area of water quality assessments and has a total of 65 papers in these areas as well as several books and/or book chapters. Dr. Adams served on the EPA SAB Ecological Processes and Effects Committee for 8 years and on several other SAB subcommittees. Additionally, he has served on the National Marine Board committees reviewing sediment assessment approaches. Dr. Adams also serves on the EPA Superfund National Advisory Committee for Environmental Policy and Technology (NACEPT). Additionally, he has served on numerous technical peer review committees and technical workshop committees. Outside of RSAC, there have been no other S-T reviews performed by Dr. Adams. Dr. Adams received his B.S. in Biological Sciences (cum laude) in 1969 from the Lake Superior State University in Sault Ste Marie, MI. He received his M.S. in Wildlife Toxicology in 1971 from the Michigan State University, E. Lansing, MI and his Ph.D. in Aquatic Toxicology in 1976 from the Michigan State University in East Lansing, MI. He receives no grant and/or contract support.

Dr. Richard Bull

Dr. Bull is presently employed one-half time as a Professor of Environmental Sciences at Washington State University (Tri-Cities Campus) and also works as a consultant in toxicology through a sole proprietorship company (MoBull Consulting). Dr. Bull has specialized in the toxicology of and risk assessment for chemicals commonly found in drinking water. He was employed by the Environmental Protection Agency in the period 1971-1984. His last position was as Director of the Toxicology and Microbiology Division of the Health Effects Research Laboratory in Cincinnati where he managed the Health Effects Research Programs under the Safe Drinking Water Act and under the Clean Water Act for the Agency. Personal research interests were in the effects of lead on brain development and the mutagenic and carcinogenic effects of disinfection by-products. In 1984 he accepted a position with Washington State University where he taught pharmacology and toxicology. His research in the toxicology and carcinogenicity of chemicals that were contaminants or additives to drinking water continued. The National Institute of Environmental Health, the United States Air Force, the U.S. Environmental Protection Agency, NASA, the American Water Works Association, and the National Water Research Institute supported his research. The research focused largely upon the haloacetic acid by-products of chlorination and metabolites of trichloroethylene. In 1994, Dr.

Bull accepted an appointment as Senior Scientist at Pacific Northwest National Laboratory (managed by Battelle) where he remained until May of 2000. His research continued to be supported by the institutions identified above, plus projects that were funded by the U.S. Department of Energy and the Strategic Environmental Research and Development Program SERDP) of the Department of Defense. This support focused largely upon the carcinogenic activity of trichloroethylene and other chlorinated solvents. He also was instrumental in bringing projects utilizing cDNA arrays to study the changes in gene expression that occur after exposure to endocrine disrupting compounds (funded by the Institute of Environmental Health Sciences of Japan) and a subcontract with Battelle on a support contract for the National Center for Environmental Assessment of the U.S. Environmental Protection Agency. These projects have expired. His activities at Washington State University are supported by a grant from the Department of Energy's Low Dose and Low Dose Rate Radiation Effects Program. Through MoBull, a contract with the American Water Works Association Research Foundation (AWWARF) is in the final stages of negotiation and should begin in Jan, 2003). Dr. Bull's consulting involves a series of small consulting agreements. Agreements include contracts through engineering firms, universities or directly with utilities (e.g. Clayton County, GA, Tampa, West Basin Municipal Water District, National University of Singapore, the Federal District of Mexico, Australian Cooperative Research Centre for Water Quality and Treatment and the Victorian Consortium for Public Health [Monash University], Generale des Eaux, Paris, and East Bay Municipal Water District in Oakland). Much of this work deals with identifying chemical hazards that might be associated with the potable reuse of wastewater. In addition, he recently wrote an informational paper for the National Rural Water Association on the concept of thresholds. He has also served as a consultant to attorneys related to litigation surrounding drinking water contamination. However, this work does not involve the giving of expert testimony. Dr. Bull has also been involved in a variety of scientific reviews associated with specific environmental contaminants. In recent years, he chaired the NRC review of Copper in Drinking Water, the EPA SAB Drinking Water Committee's review of the Proposed Drinking Water Standard for arsenic and served on the Arsenic Rule Benefits subcommittee for the U.S. EPA's Science Advisory Board. At the behest of the National Center of Environmental Assessment of EPA, Dr. Bull published a review of potential modes of action through which trichloroethylene might produce liver cancer. He also serves on the Science Advisory Panel for the Santa Ana River Water Quality and Health Study in Orange County California and has worked with Orange County in seeking Federal Support for their research activities directed at determining processes that are effective in allowing indirect potable reuse of wastewater. He currently is the chair of the NRC Subcommittee on Assessing Toxicological Risks to Deployed Military Personnel. In more distant past he has participated in a variety of additional reviews that have been conducted by the National Research Council, the Science Advisory Board, the Science Advisory Panel of EPA, the World Health Organization, and the International Agency for Research on Cancer (IARC) that are a matter of public record.

Dr. Robin Cantor

Dr. Robin Cantor is a Principal and Managing Director of LECG, LLC, a private consulting firm providing economic and financial analysis to a broad range of public and private enterprises. Dr. Cantor also has a faculty appointment in the Part-time Program in Engineering

of the Johns Hopkins University. Since October 2001, she has been a member of the Research Strategies Advisory Committee of the EPA Science Advisory Board.

Dr. Cantor's areas of expertise include environmental and energy economics, statistics, risk management, public policy and societal decision making. She has conducted research in many issues related to environmental economics including analysis of Canadian and US nuclear policies, recycling and waste management economics, environmental externalities associated with different fuel cycles and energy technologies, private sector responses to global warming, electric power plant cost estimation and planning, auction behaviors and demand side management programs, possibilities for cost-sharing arrangements between local jurisdictions and other government agencies to clean up hazardous waste sites, social and individual valuations of non-marketed goods, and consumer and industrial product prices in the context of anti-trust and other complex litigation. Dr. Cantor has submitted analysis, testimony and affidavits in federal and state proceedings and Congressional hearings. Her publications include refereed journal articles, book chapters, expert reports, reports for federal sponsors, and a co-authored book on economic exchange under alternative institutional and resource conditions.

Dr. Cantor is Past President of the Society for Risk Analysis. From 1991 to 1996, she was Program Director for Decision, Risk, and Management Sciences, a research program of the National Science Foundation. While at NSF, she was also a Coordinator for the NSF Human Dimensions of Global Change, the NSF Methods and Models for Integrated Assessment, and the NSF/EPA Decision Making and Valuation for Environmental Policy. From 1982 until 1991, Dr. Cantor was a senior researcher at Oak Ridge National Laboratory. Dr. Cantor has a B.S. in mathematics from Indiana University of Pennsylvania and a Ph.D. in economics from Duke University.

Dr. Domenico Grasso

Domenico Grasso is the Rosemary Bradford Hewlett Professor and Founding Chair of the Picker Engineering Program at Smith College and holds adjunct faculty appointments at the Universities of Connecticut and Massachusetts and Yale University. He is an environmental engineer who studies the ultimate fate of contaminants in the environment and develops new techniques to destroy or otherwise reduce the risks associated with these contaminants to human health or natural resources, he focuses on molecular scale processes that underlie nature and behavior of contaminants in environmental systems.

Dr. Grasso holds a B.Sc. from Worcester Polytechnic Institute, an M.S. from Purdue University and a Ph.D. from The University of Michigan. He is a registered Professional Engineer in the states of Connecticut and Texas, and was Professor and Head of Department in Civil & Environmental Engineering at the University of Connecticut prior to joining Smith. He has been a Visiting Scholar at UC-Berkeley, a NATO Fellow, and an Invited Technical Expert to the United Nations Industrial Development Organization in Vienna Austria. He is currently a member of the United States Environmental Protection Agency Science Advisory Board, Past-President of the Association of Environmental Engineering & Science Professors, and Editor-in-Chief of Environmental Engineering Science. He has authored more than 100

technical papers & reports, including four chapters and two books. Federal, state and industrial organizations have supported his research work. (1/2003). Currently, he holds a research grant from the US Department of Agriculture.

Dr. Philip Hopke

Dr. Hopke, is the Bayard D. Clarkson Distinguished Professor at Clarkson University. Professor Hopke is an Associate Editor of Chemometrics and Intelligent Laboratory Systems. In October 1997, he was appointed by the Administrator of the U.S. Environmental Protection Agency (EPA) as a member of the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board (SAB). Dr. Hopke is presently Chair of the CASAC, and he also chairs the CASAC Subcommittee on Particle Monitoring. In addition, he serves on both the SAB's Executive Committee and the Research Strategies Advisory Committee. Professor Hopke is a member of the National Research Council's Congressionally-mandated Committee on Research Priorities for Airborne Particulate Matter and the Committee on Air Quality Management in the United States. He has previously served on five other NRC committees.

Professor Hopke received his B.S. in Chemistry from Trinity College (Hartford) and his M.A. and Ph.D. degrees in chemistry from Princeton University. After a post-doctoral appointment at M.I.T., he spent four years as an assistant professor at the State University College at Fredonia, NY. Dr. Hopke then joined the University of Illinois at Urbana-Champaign, and subsequently came to Clarkson in 1989 as the Robert A. Plane Professor with a principal appointment in the Department of Chemistry. He has served as Dean of the Graduate School, Chair of the Department of Chemistry, and Head of the Division of Chemical and Physical Sciences before moving to the Department of Chemical Engineering in 2000.

Dr. Hilary Inyang

Dr. Hilary I. Inyang is the Duke Energy Distinguished Professor of Environmental Engineering and Science, Professor of Earth Science and Director of the Global Institute for Energy and Environmental Systems at the University of North Carolina-Charlotte. Prior to his current position, he was University Professor, Dupont Young Professor and Director of the Center for Environmental Engineering, Science and Technology (CEEST) at the University of Massachusetts, Lowell. From 1997 to 2001, Dr. Inyang served as the chair of the Environmental Engineering Committee of USEPA's Science Advisory Board. He is a member of the National Advisory Council on Environmental Policy and Technology (Effluent Guidelines Committee) and has served on more than sixty international, national and state science/engineering panels and committees. He is currently the elected president of the newly-formed International Society of Environmental Geotechnology and has co-chaired several international conferences in the US, Brazil, China, Canada and Japan since 1995. Dr. Inyang is a former AAAS/USEPA Environmental Science and Engineering Fellow, National Research Council Young Investigator (1997) and Eisenhower Fellow of the World Affairs Council (1992/93).

Dr. Inyang's research and allied professional activities have focused on waste containment systems, contaminant leachability, soil/contaminant physico-chemical interactions, natural disaster mitigation techniques, rock fragmentation techniques for energy installations and underground space, and energy / environmental policy. He has authored/co-authored several research articles, book chapters, federal design manuals and the textbook Geoenvironmental Engineering: principles and applications, published by Marcel Dekker. He is an associate editor / editorial board member of eight refereed international journals and contributing editor of three books, including the United Nations Encyclopedia of Life Support Systems (Environmental Monitoring Section). Dr. Inyang holds a Ph.D. in geotechnical engineering and materials, with a minor in mineral resources, from Iowa State University.

Dr. George Lambert

Dr. Lambert is an Associate Professor of Pediatrics and Associate Director of the Clinical Research Center at the UMDNJ-Robert Wood Johnson Medical School. He holds a MD degree from the University of Illinois and has had post graduate training in: Clinical Research in Neonatology, has been an Intern and Resident at the Harriett Lane Home, Johns Hopkins Hospital, Baltimore, Md, He was also a Pharmacology Fellow at Children's Hospital of Philadelphia, PA. Dr. Lambert is certified by the American Board of Pediatrics, 1979 & 1980; Neonatal/Perinatal Medicine, 1980 and as an Instructor, Neonatal Resuscitation, 1989

Dr. Lambert is a member of the Environmental and Occupational Health Sciences Institute (EOHSI), UMDNJ-Robert Wood Johnson Medical School and an Adjunct Associate Professor of Pharmacy in the College of Pharmacy of Rutgers, The State University of New Jersey. He is also a member of the Cancer Institute of New Jersey, and Director of the Center for Child and Reproductive Environmental Health, Director, NIH / USEPA Center for Childhood Neurotoxicology and Exposure Assessment, and the Director, Pediatric Clinical Research Center, UMDNJ- Robert Wood Johnson Medical School.

Dr. Lambert has served as a consulting expert to a number of professional and governmental organizations including: the Neuropharmacology Division of FDA, the U.S. Congress, TSCA Interagency Testing Committee, Department of Energy, Oakridge National Laboratory, Division of Chemical Assessment, Office of Orphan Products Development, FDA; NICHD's National Neonatal Collaborative Project. He is a Member, Committee on Drugs, American Academy of Pediatrics, (National Committee), a Member - Human Health Effects Committee of the Joint (U.S. and Canadian) Commission on the Great Lakes, a consultant to the World Health Organization, Environmental Toxicology in Children. He has served on a number of US EPA Science Advisory Board panels including the Dioxin Reassessment Panel. Dr. Lambert is a Fellow of the American Academy of Pediatrics

Dr. Lambert's grants include: Since 1998: New York Health Department NIEHS Award; NIEHS/US EPA Superfund Center, Co-Investigator - Mohawk Project; NIEHS Center of Excellence (M. Gallo, PI); NIEHS training Grant in Toxicology (K Reuhl, PI); US EPA - Effect of in utero exposure to PCB's on Sexual Maturation' NJ DHHS / CDC - Hypospadism and Xenoestrogen exposure in humans; NIEHS- Pharmacogenetics of environmental chemical

related toxicities (JY Hung, PI); Cancer Commission of New Jersey – Effects of Herbal products on sex hormone synthesis and metabolism; NJ Department of Environmental Protection – Effects of Eating Newark crabs on human health; NIEHS / USEPA Children Center for Environmental Health and Disease Prevention- Center for Childhood Neurotoxicology and Exposure Assessment; NCI Program Project: Tea Cancer Chemoprevention (PI CS Yang); NIEHS – The Effects of World Trade Center on human health (PI M. Gallo --Dr Lambert's Project: The effects of WTC on Reproductive Outcome.)

Dr. Maria Morandi

Dr. Morandi is an Assistant Professor of Environmental Sciences and Occupational Health at the School of Public Health of the University of Texas – Houston Health Science Center. She served as member of the Integrated Human Exposure Assessment Committee (formerly the Indoor Air and Total Human Exposure Assessment Committee) of the EPA Science Advisory Board during 1992 and 1998, and has served as a member of the Research Strategies Advisory Committee since 1998. Dr. Morandi has also served as member or chair of several EPA program review panels, the Agency for Toxic Substances Board of Scientific Councilors, and the National Institute of Occupational Health Study Section.

Dr. Morandi's areas of research interest include development of sampling and analytical methods for indoor, outdoor and personal monitoring of air pollutants in community and work environments, exposure assessment, exposure modeling, and health effects from exposure to airborne contaminants and related cellular and molecular mechanisms of action. Dr. Morandi received a BS degree in Chemistry form the City College of New York in 1978. She received M.S. and Ph.D. degrees in Environmental Health from the Norton Nelson Institute of Environmental Medicine of New York University Medical Center in 1982 and 1985. She is also certified in the practice of industrial hygiene by the American Board of Industrial Hygiene.

Dr. James Watson, Jr.

Dr. James E. Watson, Jr. is a Professor Emeritus in the Department of Environmental Sciences and Engineering at the University of North Carolina at Chapel Hill. His principal research interests relate to environmental radioactivity and radioactive waste management. He has conducted numerous studies of radon, both indoors and in water. He received the University's Underwood and McGavran Awards for excellence in teaching and the Greenberg Alumni Endowment Award for excellence in teaching, research, and service.

He is a past president of the Health Physics Society, the national radiation safety society, and a past chairman of the Radiological Health Section of the American Public Health Association. He has served as a National Lecturer for Sigma Xi, on National Academy of Sciences committees studying radioactive waste management, on the Centers for Disease Control and Prevention's Advisory Committee for Energy-Related Epidemiologic Research, as chairman of the Environmental Protection Agency's Radiation Advisory Committee, and as chairman of the North Carolina Radiation Protection Commission. Dr. Watson receives no research funding. He received his undergraduate education in nuclear engineering at North

Carolina State University. He holds a M.S. degree in Physics from North Carolina State University and a Ph.D. in Environmental Sciences and Engineering from the University of North Carolina at Chapel Hill.

Dr. Lauren Zeise

Dr. Lauren Zeise is Chief of Reproductive and Cancer Hazard Assessment within the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment. She came to state service in 1988 and has served in that position since 1991. In that position she oversees a variety of the state's cancer, reproductive and ecological risk assessment activities. Her group evaluates and provides advice on cancer, reproductive and ecological risks posed by environmental contaminants, and develops policy guidance for conducting such assessments. The group also conducts scientific evaluations mandated by Proposition 65 and evaluates the risks from use of drugs, cosmetics, gasoline and other products. It is also developing the state's guidance on evaluating risks stemming from the exposure of the young to carcinogens. She Chaired California's Comparative Risk Project Human Health Committee, and oversaw the external review of the State's risk assessment practices, policies and guidelines. She has authored over 200 reports on environmental health risks for the State of California. Dr. Zeise has been involved in the evaluation and review of a variety of risk assessment issues.

Dr. Zeise has served on various committees of the EPA's Science Advisory Board (SAB), National Institute of Medicine, National Research Council (NRC), National Toxicology Program's Board of Scientific Counselors, the NRC Board of Environmental Science and Technology, and the former Office of Technology Assessment. She served on the EPA Board of Scientific Counselor's subcommittee reviewing PM research. Currently she serves on the SAB Research Strategies Advisory Committee, NRC Committee on Air Quality Management in the United States, NRC Committee on Toxicology, NRC Committee on EPA Star Grants Program, IOM Committee on Assessment of Wartime Exposure to Herbicides in Vietnam, the IOM Board on Health Promotion and Disease Prevention, and EPA FQPA Science Review Board. She is a member and fellow of the Society of Risk Analysis and is on the editorial board for that society's journal. The National Cancer Institute Smoking and Tobacco Smoke Monograph Health Effects of Environmental Tobacco Smoke was conceived and developed under her editorial direction. She is co-author of the recently released International Agency for Research on Cancer monograph Quantitative Estimation and Prediction of Cancer Risk. Her research has focused on cancer risk assessment methodology and applications. All research funding is from her employer. She received her doctorate from Harvard University in 1984.